IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

NOVARTIS PHARMACEUTICALS CORPORATION, 59 Route 10, East Hanover, New Jersey 07936, *Plaintiff*, v. GENTNER DRUMMOND, in his official capacity as ATTORNEY GENERAL OF OKLAHOMA, 313 NE 21st Street, Oklahoma City, OK 73105, *Defendant*.	Civil Action No.

VERIFIED COMPLAINT

Novartis Pharmaceuticals Corporation (Novartis) brings this Complaint against Defendant Gentner Drummond, in his official capacity as Attorney General of Oklahoma, seeking to enjoin the enforcement of Oklahoma's recently enacted H.B. 2048. Novartis alleges as follows:

PRELIMINARY STATEMENT

1. Under a federal law known as the 340B Program, pharmaceutical manufacturers must offer to sell certain drugs at low prices to statutorily defined types of healthcare providers. The 340B Program includes a comprehensive system of pricing rules, compliance obligations, and enforcement mechanisms surrounding that "must offer" requirement.

The program takes its name from the section of the federal Public Health Service Act containing its seminal language.

2. Everything about the 340B Program is federal. It is solely a creation of Congress, fashioned to address an unintended consequence of the Medicaid Drug Rebate Program, another federal drug-pricing program Congress had recently created. H.R. Rep. No. 102-384(II), at *9, 12. Congress mandated that the 340B Program be "superintended" by the federal Health Resources & Services Administration (HRSA), which is supposed to remain "in control" of its "drug-price prescriptions." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113–114 (2011). In the 340B statute, Congress delineated the entities entitled to receive the 340B discount, the circumstances in which it must be given, and the penalties available when it is not. And to give HRSA tight reins, Congress created a "unitary administrative and enforcement scheme" meant to "centralize[ ] enforcement in the government." *Id*. at 119–120 (quotation omitted).

3. In recent years, the 340B Program has ballooned from a niche safety-net program affecting a small minority of healthcare providers into the largest healthcare program most people have never heard of. Almost two-thirds of U.S. hospitals now derive revenue from the program, and the total volume of 340B sales has increased to ten times its size in 2010. Much of that apparent growth has been fueled by the birth of a cottage industry of middlemen that help healthcare providers exploit the 340B Program and maximize revenue from it—in exchange for their share of the profits.

4. Most relevant here are so-called "contract pharmacies": a type of for-profit pharmacy that contracts with a covered entity in order to expand the volume of discounts the covered entity may claim. Contract pharmacies were not part of the 340B Program's original design. But some covered entities claimed they could not participate in the program because they lacked an in-house pharmacy. HRSA issued early guidance allowing covered entities to contract with one outside pharmacy, essentially to serve as its in-house pharmacy, and the 340B Program proceeded in that manner for many years. But in 2010, HRSA began allowing covered entities to contract with an unlimited number of pharmacies—regardless of where they are located—and this move changed the 340B Program dramatically. Some covered entities now purport to have hundreds of contract pharmacies in multiple states.

5. Contract pharmacies are based on an accounting fiction that goes hand-in-hand with a method of claiming 340B pricing called the "replenishment" model. Under the replenishment model, pharmacies purchase drugs at the commercial price and dispense them to customers in the normal course. Pharmacy customers pay standard, non-discounted prices price under the replenishment model—usually whatever co-pay their insurer generally charges them. Later, a third-party administrator culls through claims data and purports to match up the pharmacy's dispenses with covered entities' patient lists, applying an opaque set of criteria not known to manufacturers. If the third-party administrator finds what it claims to be a match, the covered entity deems that unit eligible for the 340B discount—even though the drug itself was initially purchased at the commercial price. And

that administrator (like contract pharmacies) has every incentive to "find" matches because it gets paid based on the number of hits it purports to identify.

6. To effectuate a retroactive discount, the covered entity typically orders a second "replenishment" unit at the low 340B price for delivery to the pharmacy. The pharmacy then intermingles the 340B-priced unit in its inventory with commercially priced units, to be dispensed to whoever next walks in the door with that prescription—whether or not that person was a patient of the covered entity.

7. Contract pharmacy arrangements therefore have nothing to do with patient access to drugs, or how much patients pay for their drugs. Patients are able to fill their prescriptions for these same drugs at the same pharmacies at the same price whether or not covered entities engage in the accounting fiction espoused by the replenishment model.

8. Covered entities have no obligation to pass on 340B savings to their patients, and they generally do not. Instead, they bill insurers and government payors for the full price of the drug and pocket the difference—and most covered entities need never explain what they do with those profits. The purported "patients" often do not know they have "participated" in the program at all. In short: The only people who benefit from the contract pharmacy arrangement are covered entities, contract pharmacies, and the third-party administrators who service them. Patients get the same drugs at the same prices at the same locations, whether or not their pharmacy is deemed a contract pharmacy or their transaction is at some point deemed a 340B-eligible sale.

9. Contract pharmacies have fueled the 340B Program's breakneck growth—most of which has occurred outside the boundaries Congress drew for the program. That is because contract pharmacies create the kind of pricing opacity that allows program misuse to thrive, with predictable results: The 340B Program has been beset by fraud, waste, and abuse, as the federal government and many private analysts have repeatedly found.

10. With that as backdrop, both the D.C. Circuit and the Third Circuit have recognized that the federal 340B statute gives manufacturers power to place reasonable conditions on contract pharmacy arrangements in order to rein in this abuse. *Novartis Pharms. Corp. v. Johnson,* 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023). In particular, in a lawsuit brought by Novartis, the D.C. Circuit expressly held that federal law does not require manufacturers to recognize an unlimited number of contract pharmacy arrangements in order to comply with federal law. *Novartis*, 102 F.4th at 459.

11. In light of that ruling, Novartis began limiting contract pharmacy arrangements to something closer to their historical role in the 340B Program. Novartis also took steps to increase program transparency and accountability. Corporate beneficiaries of unlimited contract pharmacy arrangements—contract pharmacies and other middlemen, but emphatically not patients—have fought back by trying to come up with creative ways to try to keep the 340B spigot overflowing.

12. Enter H.B. 2048. The new Oklahoma law purports to force manufacturers to do what the federal courts found Congress intentionally gave manufacturers the power to

choose not to do: recognize unlimited contract pharmacy arrangements, with the dramatic expansion of 340B pricing that entails. H.B. 2048 would turn federalism on its head; states cannot override Congress's policy choices—especially in a closed system like 340B.

13. H.B. 2048 is a state drug-pricing statute. It requires manufacturers to recognize an unlimited number of contract pharmacy arrangements—thus greatly expanding the amount of 340B discounts manufacturers must provide in Oklahoma, including ones the federal statute does not require. To recognize a contract pharmacy is to give the covered entity power to sweep ordinary drug sales that would otherwise occur outside the 340B Program into the program's ambit. And this is solely an issue of price, not delivery. The exact same drugs at issue are already being delivered to the same pharmacies, and the same sales to customers at the same prices would occur regardless of H.B. 2048. The only thing that distinguishes a "340B" drug from a non-"340B" drug under H.B. 2048 is the discount a covered entity—not a patient—claims on it after it is dispensed.

14. H.B. 2048 also contains its own enforcement scheme—and it authorizes potentially drastic sanctions. In this way, H.B. 2048 replaces Congress's "unitary" design with a fractal set of overlapping and potentially contradictory adjudications. That directly contravenes the Supreme Court's holding that enforcement of the 340B statute rests with the federal government alone. *Astra*, 563 U.S. at 119–120. Both the significant expansion of penalties and the decentralized nature of the enforcement scheme improperly override the plain language of the 340B statute, congressional intent, and binding Supreme Court authority.

15. H.B. 2048 repeatedly conflicts with Congress's design. The Oklahoma law attempts to refashion the 340B Program by dictating who can participate, on what terms they can participate, and the consequences of noncompliance. Carried to its logical conclusion, that effort would transform the federal 340B Program into 56 separate drug-pricing programs—one for each state, inhabited territory, and the District of Columbia. That is not the law Congress passed, and the Supremacy Clause of the U.S. Constitution does not permit that result.

16. None of this is how Congress intended the 340B Program to work. For starters, the 340B Program is a paradigmatically federal field. The overwhelmingly federal nature of this subject is apparent from the face of H.B. 2048. It is impossible to explain what H.B. 2048 does without explaining the federal 340B Program first; H.B. 2048 defines what it means by a "340B entity" or a "340B" drug by cross-referencing the 340B statute. That unmistakably federal nature means that Congress has created an area for its exclusive governance, and states may not tinker with its requirements as they see fit.

17. H.B. 2048 also violates the dormant Commerce Clause. The state law reaches beyond Oklahoma's borders by capping the prices that out-of-state manufacturers can charge their out-of-state wholesalers. It discriminates against non-Oklahoma economic interests by forcing the out-of-state pharmaceutical industry to subsidize in-state hospitals and pharmacies. And it burdens interstate commerce by subjecting manufacturers to a patchwork of fractalized state regulation—all without providing any legitimate local benefit.

18. Recognizing the legislation's legal defects, Governor Kevin Stitt vetoed H.B. 2048. Governor Stitt explained that the 340B Program "is in deep need of reform *at the federal level*," while categorizing H.B. 2048 as a form of "overreach." Office of Governor J. Kevin Stitt, *Gov. Stitt's 2025 Veto List* (last visited June 30, 2025) (emphasis added), https://tinyurl.com/ycxurmc6. Exactly right. But the Oklahoma legislature nevertheless proceeded to enact H.B. 2048 over the governor's veto without resolving any of its unconstitutional elements.

19. Absent immediate judicial intervention enjoining H.B. 2048, Novartis will suffer irreparable harm. Once the law takes effect on **November 1, 2025**, Novartis will risk violating Oklahoma law—and incurring serious penalties—merely by maintaining a 340B policy with reasonable guardrails that have already been declared lawful by federal courts applying the 340B statute. If H.B. 2048 is not enjoined, that irreparable harm will include an ongoing loss of Novartis's constitutional rights and unrecoverable administrative costs as Novartis scrambles to navigate a motley, continuously shifting regulatory landscape. Novartis therefore requests a preliminary injunction enjoining enforcement of H.B. 2048.

PARTIES

20. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized in Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Novartis's mission is to reimagine medicine to improve and extend people's lives.

21. Defendant Gentner Drummond is the Attorney General of Oklahoma. He is responsible for administering and enforcing the relevant provisions of H.B. 2048. Defendant Drummond maintains an office at 313 NE 21st Street, Oklahoma City, OK 73105. He is sued in his official capacity only.

JURISDICTION AND VENUE

22. This Court has jurisdiction under 28 U.S.C. § 1331, because this civil action arises under the laws of the United States, and under 28 U.S.C. §§ 2201–02, because this is an actual, justiciable controversy as to which Novartis requires a declaration of its rights by this Court and injunctive relief to prohibit Defendant from violating the U.S. Constitution.

23. This Court also has inherent equitable power to enjoin the actions of state officials that violate the U.S. Constitution and federal law. *Ex parte Young*, 209 U.S. 123, 159–160 (1908); *Petrella v. Brownback*, 697 F.3d 1285, 1293–94 (10th Cir. 2012).

24. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)(1) and (2) because Defendant resides in this district and because a substantial part of the events giving rise to Novartis's claims occurred in this district. The challenged state law also purports to govern contract pharmacy arrangements in this district.

FACTUAL BACKGROUND

I. Statutory and Regulatory Background

The 340B Program

25. When Congress created the Medicaid Drug Rebate Program, it inadvertently disincentivized drug manufacturers from voluntarily offering reduced prices to the

Department of Veterans Affairs and to charitable hospitals (as they had previously been doing). H.R. Rep. No. 102-384(II), *9–10 (1992); Milt Freudenheim, *Big Costs Imposed on Drug Makers*, N.Y. Times (Nov. 6, 1990) at D2, https://tinyurl.com/368umt5y. Congress enacted the 340B Program in 1992 to undo that disincentive. H.R. Rep. No. 102-384(II), *12 (1992); Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

26. Federal law defines a covered entity in precise terms. The statute lists fifteen types of healthcare providers that can be covered entities. 42 U.S.C. § 256b(a)(4). When Congress created the program, only about 1,000 covered entities could receive the heavily reduced 340B ceiling prices.[1] The statute's enumeration of covered entities continues to reflect the program's narrow purpose: to support care for specific types of under-resourced patients. *Id.*; *see also, e.g.*, 42 U.S.C. § 256b(a)(4) (listing AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, black-lung clinics, and Native Hawaiian Health Centers, among others).

27. The 340B Program therefore serves a specific, deliberately balanced federal purpose: to regulate drug prices in a narrow category of purchases to a narrow and specified list of entities. Manufacturers must offer covered outpatient drugs to providers called "covered entities" at a deeply reduced price, known as the "ceiling price." 42 U.S.C. §§ 256b(a)(1), (a)(4), (b)(1).

[1] Ryan P. Knox et al., *Outcomes of the 340B Drug Pricing Program*, 4(11):e233716 JAMA Health F., at 4 (Nov. 2023), https://tinyurl.com/mwrfzwym.

28. Federal law prescribes a statutory formula for calculating 340B ceiling prices. 42 U.S.C. § 256b(a)(2); 42 C.F.R. § 10.10(a). Ceiling prices can drop as low as a penny per drug. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,215 (Jan. 5, 2017). Covered entities, however, have no obligation to pass those savings on to patients,[2] and they mostly do not.[3]

29. All of this comes at a great cost to manufacturers. The statute therefore includes a number of protections to avoid abuse and limit the burden on drugmakers. Most fundamentally, manufacturers need not offer 340B prices to anyone other than a covered entity. 42 U.S.C. § 256b(a)(1).

30. In addition, a covered entity must meet three statutory requirements to qualify for a 340B discount. First, covered entities may not "duplicate" discounts by requesting 340B prices on drugs that will also be subject to a Medicaid rebate. *See* 42 U.S.C. § 256b(a)(5)(A). Second, covered entities cannot "divert" a 340B product by dispensing it to anyone besides a "patient" of the covered entity. *Id.* § 256b(a)(5)(B). These limitations reflect Congress's awareness of the dangerous arbitrage incentives created by the 340B Program: Covered entities can sell discounted drugs for much more to patients and payors, including Medicare and Medicaid. These anti-duplication and anti-diversion provisions are intended to ensure that 340B pricing hews to its purpose. Third,

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[2] Rena M. Conti & Peter B. Bach, *Cost Consequences of the 340B Drug Discount Program*, 309 JAMA 1995, 1995 (2013), https://tinyurl.com/yc2t8b35.

[3] Rory Martin & Kepler Illich, IQVIA, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?* 11–12 (2022), https://tinyurl.com/4bfbz7yz.

covered entities must permit manufacturers to audit records that "directly pertain to the entity's compliance" with the anti-duplication and anti-diversion prohibitions. *Id.* § 256b(a)(5)(C). This audit requirement is intended to give teeth to the first two compliance requirements and to ensure that covered entities are receiving 340B discounts only for eligible transactions. *Id.* § 256b(a)(5)(C).

Federal Enforcement Mechanisms

31. The federal 340B statute provides for two enforcement mechanisms. The federal government can levy civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the ceiling price for drugs dispensed to 340B patients. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). Manufacturers face liability of up to $7,034 "for *each instance* of overcharging a covered entity that may have occurred." *Id.* (emphasis added); *see also* Annual Civil Monetary Penalties Inflation Adjustment, 89 Fed. Reg. 64,815, 64,819 (Aug. 8, 2024) (adjusting the statutory amount for inflation). Each "order" that ultimately "results in a covered entity paying more than the ceiling price" is an "instance of overcharging." 42 C.F.R. § 10.11(b).

32. Federal law also provides for an administrative dispute resolution (ADR) process, in which both covered entities and manufacturers have a pathway to enforce 340B Program compliance. 42 U.S.C. § 256b(d)(3). HHS has promulgated detailed ADR regulations. 340B Drug Pricing Program, 89 Fed. Reg. 28,643 (Apr. 19, 2024); 42 C.F.R. § 10.20 *et seq*. Under those regulations, a covered entity may bring an ADR claim against a manufacturer alleging that the "manufacturer has limited the covered entity's ability to

purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21(a)(1). HHS's procedural regulations include a three-year statute of limitations, *id.* § 10.21(b)(1), joinder rules, *id.* § 10.21(c), timelines for responses, § 10.21(e), covered entities' ability to request discovery from manufacturers, *id.* § 10.22, and a mechanism for appealing adverse decisions to the HRSA Administrator, *id.* § 10.24. A final decision by the HRSA Administrator constitutes final agency action reviewable in federal court under the Administrative Procedure Act. *See id.* § 10.24(e); 5 U.S.C. § 704.

Contract Pharmacy Arrangements

33. At the 340B Program's inception, covered entities dispensed 340B-priced drugs only through in-house pharmacies. That is unsurprising. The 340B statute's "language suggests that [Congress] had in mind one-to-one transactions between a covered entity and a drug maker." *Sanofi*, 58 F.4th at 704.

34. Covered entities lacking an in-house pharmacy eventually sought the ability to contract with an outside pharmacy in order to claim access to 340B discounts. In 1996, HRSA finalized guidance for the purpose of permitting each covered entity lacking an *in-house* pharmacy to contract with one *outside* pharmacy, so long as the pharmacy agreed to abide federal compliance standards. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

35. At first, covered entities and their contract pharmacies mostly used a physical-inventory model. That is, a covered entity or its contract pharmacy physically

segregated units purchased at 340B prices from units purchased at commercial prices. Each entity then determined whether a prescription was 340B-eligible before dispensing a drug.[4] If the prescription was 340B-eligible, the covered entity dispensed a 340B-priced unit. Otherwise, it dispensed a commercially priced unit.

36. Over time, covered entities have shifted toward a "replenishment" model. The replenishment model creates a shell game where it becomes all but impossible to trace demands for 340B pricing back to the units that ostensibly triggered the statute in the first place. Covered entities can exploit that opacity to claim 340B pricing in situations where the federal statute does not authorize a discount, while minimizing the risk of detection. So it is no coincidence that the replenishment model is now the dominant method of offering 340B pricing in Oklahoma (and nationwide).

37. Retroactive pricing is the central pillar of the replenishment model. In broad strokes (there are several different variations on this theme), that retroactivity works like this:

a. The pharmacy purchases, at commercial prices, a pre-set amount of drug called a "full package." The pharmacy places the full package in common inventory—that is, the pharmacy maintains no distinction between "340B" drugs and other drugs on the pharmacy shelf.

[4] *See* HHS OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 5 (Feb. 4, 2014) (Contract Pharmacy Report), https://tinyurl.com/2nmdrcey.

b. Over time, the pharmacy dispenses drugs from common inventory whenever a customer arrives at the pharmacy counter with a prescription. The pharmacy does so without regard to whether the customer is a patient of the covered entity or whether the prescription is 340B-eligible.

c. A third-party administrator gathers claims data from both covered entities and contract pharmacies to analyze prior dispenses to assess which of them it thinks *could* have been 340B-eligible. That call is made through an opaque algorithm that drug manufacturers never see. And the third-party administrator is incentivized to "find" 340B eligibility as often as possible because it (like contract pharmacies) gets paid based on the number of "matches" it reports.

d. When the third-party administrator purports to identify enough 340B-eligible transactions to make a full package, the covered entity typically orders a "replenishment" package of the drug at the 340B price.

e. The pharmacy places the replenishment drug purchased at the 340B price in its common inventory, to be dispensed to the next customer who walks in the door (whether a patient of the covered entity or not, and whether eligible to receive a 340B drug or not). And the cycle begins all over again.

38. In short, the replenishment model is based on an accounting trick. The upshot is that 340B drugs are dispensed without regard to 340B eligibility. A unit may receive 340B pricing based on the identification of a previously dispensed drug—often one dispensed long ago—as ostensibly 340B-eligible. But a pharmacy that receives 340B-priced drugs does not treat that inventory as belonging to the 340B Program, and it routinely acquires the same drugs at commercial prices irrespective of the 340B Program. As a logical outgrowth of the replenishment model, drugs purchased at 340B prices are not necessarily dispensed to patients of covered entities, nor does a covered entity necessarily maintain title to them.[5] Pharmacy customers, for their part, almost always pay whatever price their insurance ordinarily requires, without regard to whether their prescription was the trigger for 340B eligibility. The replenishment model treats 340B status like a virtual baton that is passed from unit to unit, depending on whatever narrative suits covered entities' needs at a given moment. In this world, there is no such thing as a singular "340B drug" for all purposes.

39. The "replenishment" scheme and its inevitable furtherance of fraud and abuse have not always been a part of the 340B Program—far from it. Covered entities originally could dispense only from their in-house pharmacies. After that, HRSA adhered

[5] *E.g.*, 340B Contract Pharmacy Services Agreement – ReCept Pharmacy at 5, § 3.2 (Dallas Cnty. Comm'rs Ct.) ("County shall purchase 340B Drugs through a written contract with the Supplier and shall hold title to such drugs from the time the Supplier fills the order from ReCept [(the contract pharmacy)] made on behalf of the County until the time that ReCept takes delivery of the drugs."), https://bit.ly/4gDGvbq; *see also* Pharmacy Services Agreement Between the County of Monterey and CVS Pharmacy, Inc. at 9, https://bit.ly/3Dhg9xo.

to its one-contract-pharmacy limit for many years, and even that concession was originally only "designed to facilitate program participation for those eligible covered entities that do not have access to appropriate 'inhouse' pharmacy services." 61 Fed. Reg. at 43,555. Over time, however, covered entities began pressuring HRSA to relax that longstanding restriction. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (March. 5, 2010).

40. In 2010, HRSA opened the floodgates. It allowed covered entities to "pursue more complex arrangements that include multiple pharmacies," essentially placing no limit on the number of contract pharmacies that could participate in the 340B Program. *Id.* at 10,277. HRSA's decision spawned the contemporary 340B Program: an ever-growing sprawl of contract pharmacies selling drugs to anyone with a prescription, and then retroactively deeming some of those sales 340B sales based on opaque criteria, all nominally on behalf of covered entities that may be many miles away.[6]

41. Contract pharmacies and third-party administrators have a strong incentive to report transactions as being supposedly 340B-eligible. Each middleman gets a cut of the 340B funds, which shapes how the program plays out in practice: As the U.S. Court of Appeals for the D.C. Circuit has correctly noted, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial

[6] *See* Sayeh Nikpay et al., *Trends in 340B Drug Pricing Contract Growth Among Retail Pharmacies from 2009 to 2022*, 4(8):e232139 JAMA Health F., at 1–2 (Aug. 4, 2023), https://tinyurl.com/558msvnk.

incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457–458.

42. The incentives underlying the replenishment model and unlimited contract pharmacy arrangements have made big business out of purporting to identify 340B-eligible transactions. A handful of massive for-profit pharmacy chains and pharmacy benefit managers now dominates the contract pharmacy industry.[7] Third parties siphon a sizeable share of these funds that Congress had intended to help non-profit hospitals located in underserved communities: About 16 percent of *all* 340B "revenue" currently fills the coffers of these for-profit third parties.[8] That share is so large that some covered entities reported a "net loss" on 340B transactions "as a result of their high external operational costs." *Id.* at 25. Meanwhile, Walgreens and CVS warn investors that changes to contract pharmacy arrangements would materially hurt their bottom lines.[9]

43. The intermediaries' work occurs largely in secret. Under the replenishment model, covered entities typically do not tell manufacturers which specific transactions they have identified as 340B-eligible or why—either before or after placing a "replenishment"

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[7] Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340BContract Pharmacy Market*, Drug Channels (July 11, 2023), https://tinyurl.com/5n6hfmtd.

[8] Minnesota Dep't of Health, *340B Covered Entity Report* 9 (Nov. 25, 2024), https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

[9] CVS Health, *2023 Annual Report* 26 (Feb. 7, 2024) ("[A] reduction in the use of the Company's administrative services by Covered Entities . . . could materially and adversely affect the Company."), https://tinyurl.com/kdkx49t2; Walgreens Boots Alliance, *2023 Annual Report* 33 (Oct. 12, 2023) (similar), https://tinyurl.com/ypnas5zt.

order. In other words, the covered entities and their cohorts are demanding that manufacturers offer massive discounts without providing even the most basic documentation showing the sale's eligibility for this discount. No legitimate business would or could operate in this manner.

44. As a result, "[t]ransparency in the 340B Program is being compromised . . . by a lack of publicly available data, including" data showing "which claims are 340B-eligible." Martin & Illich, *supra* n.3, at 12. Even "patients are often unaware that they have participated in the 340B Program at all."[10]

Runaway Growth and Compliance Problems

45. The predictable result of all this clandestine profit-seeking has been accelerating growth of the 340B Program, driven largely by misuse.

46. When HRSA unleashed unlimited contract pharmacy arrangements in 2010, total 340B spending was about $6.6 billion.[11] That volume multiplied *tenfold* by 2023, reaching $66.3 billion.[12] In just the last five years of available data, 340B volume grew by *over 129 percent*.[13] The 340B Program is now the second-largest federal drug-pricing

[10] Neal Masia, Alliance for Integrity & Reform, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019* 2, https://tinyurl.com/7cc3dw2t.

[11] Rebecca Sachs & Joshua Varcie, Congressional Budget Off., *Spending in the 340B Drug Pricing Program, 2010 to 2021* 2 (June 17, 2024) (CBO Report), https://tinyurl.com/ykt2d4v9.

[12] Adam Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022*, Drug Channels (Oct. 22, 2024), https://tinyurl.com/mryxdh34.

[13] Rory Martin & Harish Karne, IQVIA, *The 340B Drug Discount Program Grew to $124B in 2023* (May 31, 2024), https://tinyurl.com/3b8zcu5a.

program, behind only Medicare Part D (and not by much).[14] Thus, it is larger than Medicaid and Medicare Part B—even though access to those programs is supposed to be the incentive for manufacturers to participate in the 340B Program. *See* 42 U.S.C. §§ 1396r-8(a)(1), (5)(A).

47. That growth in the 340B Program was largely driven by the explosion of contract pharmacy arrangements. The federal Government Accountability Office (GAO) reports that only about 1,300 such relationships existed in 2010. GAO, *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 at 2 (Jan. 2020) (GAO 2020 Report), https://www.gao.gov/assets/gao-20-212.pdf. The same number is now about 35,000.[15]

48. The explosion of contract pharmacy arrangements has created serious federal compliance concerns, as federal agencies have repeatedly recognized. For example, GAO has tied the increase in contract pharmacy arrangements to increased "potential for duplicate discounts." *See* GAO 2020 Report, *supra* ¶ 47, at 2; *see also id.* at 32–33 (noting that dispenses at contract pharmacies often do not produce data that allows stakeholders "to detect potential duplicate discounts"). HHS OIG, too, found that the proliferation of contract pharmacies "create[s] complications in preventing" both unlawful "diversion" and "duplicate discounts." Contract Pharmacy Report, *supra* n.4, at 1–2.

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[14] Ashley Flint et al., *340B Purchase Data Highlights Continued Program Growth*, Avalere Health (Oct. 24, 2024), https://tinyurl.com/yzwt66mf.

[15] Milena Sullivan et al., *Contract Pharmacy Trends May Help Inform 340B Reform Debate*, Avalere Health (June 10, 2024), https://tinyurl.com/3umyyrvc.

49. To see why, consider that "contract pharmacies are more likely" than in-house covered-entity pharmacies "to serve both patients of covered entities and others in the community." GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 at 28 (Sept. 2011), https://www.gao.gov/assets/d11836.pdf. When that fact is combined with the opacity and retroactive nature of the replenishment model, it results in ample opportunities to claim 340B pricing inappropriately. The D.C. Circuit has noted a helpful example: "[S]uppose a physician practices at a covered entity and somewhere else. The physician writes a prescription for a patient of his private practice. Yet the contract pharmacy, connecting the physician to the covered entity, classifies the prescription as eligible for the discount." *Novartis*, 102 F.4th at 458.

50. Under those circumstances, 340B noncompliance has become routine. In just one seven-year span, HHS audits found over 1,500 instances of 340B Program noncompliance, including 429 instances of duplication. GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 at 14 (Dec. 2020) (2020 GAO Report), https://www.gao.gov/assets/gao-21-107.pdf. Given the low volume of government audits,[16] those findings suggest huge rates of noncompliance.

[16] HHS audits only about 200 covered entities per year. Decl. of Krista M. Pedley, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-CV-634 (D.N.J. July 6, 2021), ECF No. 93-2 ¶ 6. HHS also does not audit for duplication in Medicaid managed care, which accounts for the majority of Medicaid utilization. GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 at 25 (June 2018).

The available evidence confirms as much: In 2021, "[m]ore than 60 percent of audited covered entities had at least one adverse finding."[17] In short, 340B "discount errors" have become "likely" and "duplicate discounts" are now "quite common."[18]

51. Unlawful duplication, in particular, has become staggering. Some analysts estimate that three to five percent of *all* Medicaid rebates now duplicate 340B pricing.[19] In 2020 alone, that rate amounted to between *$1.3 billion and $2.1 billion* in illegal duplicates. *Id.* The amount of duplication is likely much higher today because 340B purchases nearly doubled between 2020 and 2023, rising from $38 billion to $66 billion. *See* Fein, *supra* n.12.

52. The Congressional Budget Office recently found that "[t]wenty percent of the growth in 340B spending from 2010 to 2021 can be attributed to spending on drugs dispensed at contract pharmacies." CBO Report, *supra* n.11, at 8. More contract pharmacies, or fewer restrictions on contract pharmacies, means more opportunities for self-interested middlemen to "influence which prescriptions are classified as 340B."[20] That is, after all, why many covered entities partner with for-profit third parties in the first place—they "show[ ] hospitals how to . . . boost[ ] the number of prescriptions that can

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[17] Lindsay Bealor Greenleaf, *Analysis of FY 2021 HRSA 340B Covered Entity Audits*, ADVI (Feb. 23, 2023), https://tinyurl.com/yc2aktnh.

[18] House Energy & Com. Comm., *Review of the 340B Drug Pricing Program* 36 (Jan. 10, 2018) (340B House Report), https://tinyurl.com/58rpjkfv.

[19] Ashwin Mundra, *The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark*, Drug Channels (Mar. 18, 2022), https://tinyurl.com/2ewmceba.

[20] *See* Aaron Vandervelde et al., Berkely Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 8 (Oct. 2020), https://tinyurl.com/mrxxr4rn.

qualify for discounts." *See, e.g.*, Ellen Gabler, *How a Company Makes Millions off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 16, 2025), https://tinyurl.com/yv7akn6t.

53. Hospitals are particularly adept at exploiting 340B pricing spreads. One recent study found that "[h]ospitals eligible for 340B discounts obtained reimbursement-price markups that were 6.59 times . . . as high as those obtained by physician practices."[21] More contract pharmacy arrangements therefore means more money in the pockets of hospitals, third-party pharmacies, and third-party administrators. Most patients get nothing. Worse, some evidence shows "that the ability of people suffering severe economic hardship to afford needed drugs and medical care, relative to the general population, is *negatively correlated* with growth in the 340B Program."[22]

54. After a detailed investigation into how the 340B Program works on the ground, a Senate committee recently concluded that the covered entities it studied "do not pass 340B discounts directly to their patients," and that in recent years manufacturers "have seen significant increases in 340B sales to contract pharmacies compared to direct sales to hospitals and grantees." The investigation necessarily focused on select covered entities, federal grantees, and drug manufacturers, but its "findings reveal insights into how 340B revenue flows among the largest 340B participants, and how they use this revenue on

[21] James C. Robinson et al., *Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance*, 390 New Engl. J. of Med. 338, 344 (2024), https://tinyurl.com/33zvwnex.

[22] Bruce Levinson, *Measuring the Effectiveness of the 340B Program* 3–9 (Nov. 1, 2018) (emphasis added), https://tinyurl.com/3fnsr4nv.

behalf of patients."[23] Those insights culminated in the finding that "transparency and oversight concerns . . . prevent 340B discounts from translating to better access or lower costs for patients." Senate HELP Committee Report, *supra* n.23, at 38.

55. For all those reasons, contract pharmacy arrangements have nothing whatsoever to do with giving patients access to drugs, or even to discounted prices on drugs. They exist solely to benefit hospitals, pharmacies, and third-party administrators at drug manufacturers' expense.

II. Novartis's Contract Pharmacy Policies and Related Litigation

56. Novartis has long been concerned about the seemingly endless growth of contract pharmacy arrangements and their abuses of the 340B Program. It has therefore adopted policies placing reasonable limitations on contract pharmacy arrangements to mitigate their harms and to restore contract pharmacies to the place they have historically occupied in the 340B Program.

Novartis's Prior Policies and Federal Litigation

57. Novartis implemented its first contract pharmacy policy in late 2020 after notifying HRSA that it would do so. Under that policy, Novartis honored contract pharmacy arrangements only if the third-party pharmacy was within 40 miles of the covered entity. But Novartis exempted federal grantees and permitted other covered entities to request exemptions if justified by a specific need. Novartis also requested—but

[23] Senate Health, Education, Labor & Pensions Comm., *Congress Must Act to Needed Reforms to the 340B Drug Pricing Reform* 5, 9, 32 (Apr. 2025) (Senate HELP Committee Report), https://tinyurl.com/bdd24yd4.

did not require—that covered entities give Novartis basic claims data using an electronic platform.

58. Covered entities complained to HRSA. Letter from HRSA to Novartis at 1 (May 17, 2021), https://tinyurl.com/d34r9ajp. HRSA initially took the position that Novartis's policy violated the federal 340B statute. *Id.* HRSA claimed that "[n]othing in the 340B statute grants a manufacturer the right to place conditions" on offers to provide drugs at 340B prices. *Id.* So HRSA threatened Novartis with civil monetary penalties and ordered Novartis to "plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements." *Id.* at 2.

59. Novartis challenged HRSA's 2021 letter as inconsistent with the federal 340B statute. *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-CV-1479 (D.D.C. filed May 31, 2021). The U.S. District Court for the District of Columbia set aside HRSA's letter. *Id.*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). It rejected HRSA's position that the federal 340B statute "prohibit[s] . . . manufacturers from imposing any conditions on their offers of 340B-priced drugs to covered entities." *Id.* at *9 (emphasis omitted).

60. Novartis updated its contract pharmacy policy in 2023. Under that policy, Novartis would ship 340B-priced drugs directly to covered entities with an in-house pharmacy. Covered entities without an in-house pharmacy could select one contract pharmacy where Novartis would provide 340B pricing. Novartis also elected to continue recognizing contract pharmacy arrangements between covered entities and pharmacies

wholly owned and controlled by those covered entities. Novartis again requested that covered entities provide claims data electronically.

61. About a year later, the U.S. Court of Appeals for the D.C. Circuit affirmed the district court's decision setting aside HRSA's 2021 letter. *Novartis*, 102 F.4th 452. The D.C. Circuit observed that a contract pharmacy arrangement creates "a financial incentive to catalog as many prescriptions as possible as [340B-]eligible." *Id.* at 457–458. That is because it allows "[t]he covered entity, the pharmacy, and the third-party administrator [to] divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457.

62. The D.C. Circuit "reject[ed] HRSA's position that section 340B prohibits drug manufacturers from imposing any conditions" on the use of contract pharmacies. *Novartis*, 102 F.4th at 459. HRSA had argued that the statute does not expressly tell manufacturers they may impose such conditions. But the D.C. Circuit concluded that "this silence preserves—rather than abrogates"—manufacturers' discretion to do so. *Id.* at 460. Among other problems, HRSA's contrary reading would have "categorically requir[ed] manufacturers to deal with an unlimited number of contract pharmacies"—an obligation not found in the federal statute. *See id.* at 462.

63. Despite referring to statutory "silence," the D.C. Circuit did not suggest that the federal 340B statute leaves manufacturers' ability to condition 340B pricing *unregulated*. Rather, the federal 340B statute requires manufacturers to "offer each covered entity covered outpatient drugs for purchase" at or below the "ceiling price." 42

U.S.C. § 256b(a)(1). That requirement prevents manufacturers from imposing conditions so onerous that they amount to a failure to make a "bona fide offer"—for example, if the conditions "effectively increase the contract 'price,' thus perhaps nudging it above the statutory ceiling." *Novartis*, 102 F.4th at 462. But within the range of bona fide offers, the federal 340B statute affirmatively and intentionally grants "private parties" the right to "act freely" in agreeing to contractual terms. *See id.* at 460.

64. The D.C. Circuit expressly held Novartis's updated contract pharmacy policy lawful. It reasoned that limiting covered entities to in-house pharmacies or to "a single contract pharmacy . . . . neither precludes Novartis from making a bona fide 'offer' nor increases its contract 'price.' " *Novartis*, 102 F.4th at 463–464. That condition on 340B sales is "consistent with historic practices under the section 340B Program." *Id.* at 464. It is thus within the range permitted by the federal 340B statute. *See also Sanofi*, 58 F.4th at 703–706.

Novartis's Current Policy

65. Novartis further updated its contract pharmacy policy on January 1, 2025. Ex. 1 (2025 Policy). This policy differs from Novartis's 2023 policy in essentially three ways.

66. First, contract pharmacies working for covered entities subject to the policy must provide basic claims data to receive 340B-priced drugs. These data are needed to "mitigate instances of duplicative discounts" that violate federal law, and sharing them will "increase transparency" and "help maintain the integrity and sustainability" of the 340B

Program. Ex. 1 (2025 Policy) at 1. Novartis's decision to require these data was also influenced by the fact that covered entities mostly refused to provide such data voluntarily under Novartis's prior policies. It also was driven by the D.C. Circuit's recognition that manufacturers could require claims data from covered entities under the 340B statute.

67. Second, Novartis clarified that a designated contract pharmacy must be one that dispenses drugs to patients. That is, covered entities cannot designate a "central fill" pharmacy—a pharmacy that distributes product to many retail pharmacy locations—in an attempt to circumvent Novartis's one-contract pharmacy condition on 340B pricing.

68. Third, contract pharmacies wholly owned and controlled by a covered entity are no longer exempted from the policy. Novartis will not recognize arrangements between covered entities and these pharmacies unless a covered entity lacks an in-house pharmacy and designates an outside pharmacy as its single permitted contract pharmacy. Federal grantees, however, continue to be exempted.

III. Oklahoma Enacts Its Own "340B" Legislation

69. The Oklahoma Legislature recently passed H.B. 2048, a law that explicitly creates new state-level "340B" obligations. Oklahoma State Legislature, H.B. 2048 (last visited June 30, 2025), https://tinyurl.com/38tadjsn. This state law does not even attempt to conceal its federal subject matter. H.B. 2048 defines its key terms solely by reference to federal law governing the "federal 340B drug discount program." *E.g.*, Okla. Stat. tit. 36, § 5401(2).

70. Governor Stitt saw the problem with this "overreach" into federal matters. He vetoed the bill, explaining: "The program addressed in HB 2048 is in deep need of reform at the federal level to improve transparency." However, the Governor noted, "I do not believe it is the job of the legislature to insert itself into a contractual dispute and try to pick winners and losers." Office of Governor J. Kevin Stitt, *Gov. Stitt's 2025 Veto List* (last visited June 30, 2025), https://tinyurl.com/ycxurmc6.

71. Even so, the legislature overrode the veto without changing the bill. Absent judicial intervention, the law will take effect November 1, 2025.

Pricing Regulations

72. H.B. 2048 regulates drug pricing by forbidding manufacturers to "directly or indirectly" "deny, restrict, prohibit, or otherwise interfere with" "the acquisition of a 340B drug by, or delivery of a 340B drug to a 340B entity." Okla. Stat. tit. 36, § 5403(A). The statute separately defines a "340B drug" as any drug purchased "at reduced prices" by "a covered entity"—a federally defined term, as the statute acknowledges. *Id.* § 5401(1) (citing 42 U.S.C. § 256b(a)(4)). A "340B entity," H.B. 2048 announces, is any entity "authorized to participate in the federal 340B drug discount program, as described in [42 U.S.C. § 256b]" *plus* contract pharmacies themselves (a type of entity not found anywhere in the federal 340B statute). Okla. Stat. tit. 36, § 5401(2). In sum, the statute orders manufacturers to honor essentially all requests for 340B pricing for drugs that are delivered to contract pharmacies.

73. In practice, the law mandates a carte-blanche approach to the replenishment model. Notwithstanding H.B. 2048's nomenclature, under the federal statute there is no such thing as a "340B drug" and a "non-340B drug." There are only "covered outpatient drugs," which—when sold to covered entities under the terms of the federal 340B statute—are subject to discounted pricing under the federal 340B law. 42 U.S.C. § 256b(a)(1). When the state statute references a "340B drug," it is talking about a unit of drug sold at the 340B discounted price.

74. These same drugs are also routinely sold to myriad pharmacies—including the very same pharmacies covered entities purport to designate as contract pharmacies—at commercial prices. Remember that under the replenishment model, contract pharmacy arrangements are based on an accounting fiction. Pharmacies dispense drugs *they already have in their possession* and do not even try to distinguish between 340B- and non-340B-priced inventory until long after a drug has been dispensed. A third-party administrator culls through data after the fact and tries to match up dispenses to pharmacy customers with hospital patient information. If a match is purportedly found, the covered entity typically purchases a "replenishment" unit at the low 340B price and demands that it be delivered to the pharmacy, which intermingles the 340B drugs in its inventory with commercially priced units, to be dispensed to whoever walks in the door next with a prescription.

75. It isn't even clear which drug the covered entity would argue is the "340B drug"—the one that was purchased at commercial prices and dispensed by the pharmacy to a person who was purportedly a patient of a covered entity, or the "replenishment drug"

that ultimately is purchased at the 340B discount and that may be dispensed to a non-340B patient. Covered entities and contract pharmacies do not seem to care. The point is simply for those entities to claim the 340B discount on as many transactions as possible.

76. And that is what H.B. 2048 attempts to mandate, in direct contravention of what federal law requires. By forcing manufacturers to recognize an unlimited number of contract pharmacy arrangements, H.B. 2048 expands the number of transactions that trigger the 340B discount beyond the scope of federal law.

Enforcement Mechanisms

77. Manufacturers who violate H.B. 2048's sweeping provisions are subject to severe penalties. The statute grants the Attorney General authority to impose civil monetary penalties up to $10,000 "for each violation." Okla. Stat. tit. 36, § 5404(B). A violation occurs "each time a prohibited act is committed." *Id.* § 5404(C).

78. Assuming a "violation" occurs each time a manufacturer does not honor a request for 340B pricing on drugs dispensed by a contract pharmacy, the penalties could stack up quickly. H.B. 2048's objective is thus to coerce manufacturers into operating the federal 340B Program on Oklahoma's terms.

H.B. 2048 VIOLATES THE SUPREMACY CLAUSE

79. "The Supremacy Clause provides a clear rule that federal law 'shall be the supreme law of the land . . . anything in the . . . laws of any State to the contrary notwithstanding.' " *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. art. VI, cl. 2).

80. As the Supreme Court has noted, Congress created the 340B Program as an exclusively federal program. It "placed the Secretary [of HHS] (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions." *Astra*, 563 U.S. at 114. If other entities were to gain power over these requirements, "[t]hat control could not be maintained." *Id.* But that is precisely what H.B. 2048 has attempted to do: wrest control over drug pricing from federal hands and give it instead to Oklahoma regulators.

81. H.B. 2048 is preempted under both field and conflict preemption principles.

82. The Supremacy Clause forbids that result. H.B. 2048 is misguided from the start because the 340B Program is a pervasive regulatory scheme that states may not supplement or alter. In addition, H.B. 2048 impermissibly throws up several independent obstacles to accomplishing the purposes of the 340B statute and other federal statutes.

Federal Law Occupies the Field.

83. Congressional "intent to displace state law" can be inferred from a regulatory scheme "so pervasive . . . that Congress left no room for the States to supplement it" or from a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399 (quotation omitted).

84. The first step in a field-preemption analysis is to identify "the legislative field that the state law . . . implicates." *US Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1325 (10th Cir. 2010). H.B. 2048 is unusual because it does not identify any legislative field outside of federal legislation itself. Nor could it. On its face, H.B. 2048 regulates activity

under "the federal 340B drug discount program." Okla. Stat. tit. 36, § 5401(2); *see also id.* §§ 5403(A)–(B). So it is redundant to ask whether H.B. 2048 "implicates the field as occupied by federal law." *See US Airways, Inc.*, 627 F.3d at 1327. The "field" H.B. 2048 regulates *is* federal law—the contours of the obligation to provide discounted pricing under the federal 340B statute.

85. H.B. 2048 has no force or meaning outside of the federal 340B Program. If Congress were to repeal the federal 340B statute, H.B. 2048 would cease to have any effect. *See* Okla. Stat. tit. 36, §§ 5401(1)–(2) (citing 42 U.S.C. § 256b). H.B. 2048, in other words, "is inherently federal in character" because it regulates relationships that "originate[ ] from, [are] governed by, and terminate[ ] according to federal law." *Helfrich v. Blue Cross & Blue Shield Ass'n*, 804 F.3d 1090, 1105 (10th Cir. 2015) (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001)).

86. Field preemption therefore turns on whether Congress intended to regulate the program it created "to the exclusion of the states." *US Airways, Inc.*, 627 F.3d at 1325. The 340B statute's "structure and purpose," *Bradshaw v. American Airlines, Inc.*, 123 F.4th 1168, 1173 (10th Cir. 2024) (quotation omitted), shows that to be precisely what Congress intended.

87. The federal 340B statute sets up a pervasive and carefully integrated pricing scheme that interacts with other federal drug-pricing programs. Congress determined the ceiling price that manufacturers may charge to covered entities and decided which entities

are entitled to receive that benefit. *See* 42 U.S.C. §§ 256b(a)(1), (a)(4), (b)(1). Contract pharmacies are not among them. *See id.* § 256b(a)(4).

88. Congress also balanced the pricing obligations it imposed on manufacturers with corresponding requirements on covered entities. Covered entities may not exploit the program by diverting 340B-priced drugs to persons who are not "patients of the covered entity." *Id.* § 256b(a)(5)(B). And Congress directed that manufacturers should not have to provide 340B pricing that duplicates discounts it has separately required under the Medicaid Drug Rebate Program, *id.* § 256b(a)(5)(A)(i), or the Inflation Reduction Act of 2022 (IRA), *id.* § 1320f-2(d)(1).

89. To protect both covered entities and manufacturers, Congress created particular enforcement mechanisms under federal power and oversight. HRSA may directly enforce the federal statute by imposing civil monetary penalties. 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 1003.100 *et seq.* HRSA also oversees factfinding and dispute-resolution processes initiated by regulated parties. *See id.* §§ 256b(a)(5)(C)–(D) (providing for auditing of covered entities and sanctions for noncompliance); 256b(d)(3) (establishing an ADR process).

90. These enforcement mechanisms are exclusive. Congress intended to "centralize enforcement in the government." *Astra*, 563 U.S. at 119. It gave HHS "authority to oversee compliance" to ensure that the 340B Program is administered on a "uniform, nationwide basis," and it declined to permit "auxiliary enforcement" outside of the program. *Id.* at 117, 120. The intent to give a federal agency such "general authority"

over a "unified and comprehensive regulatory system" is a hallmark of field preemption. *Southwest Bell Wireless Inc. v. Johnson Cnty. Bd. of Cnty. Comm'rs*, 199 F.3d 1185, 1191 (10th Cir. 1999) (quotation omitted).

91. The federal 340B statute reflects the intent to retain federal control over even the marginal details of how 340B pricing is provided. Congress instructed HRSA to "establish[ ] a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section." 42 U.S.C. § 256b(d)(2)(B)(iv). The federal statute regulates every part of the transaction chain, from drug availability to pricing to delivery to enforcement and dispute resolution.

92. In sum, Congress intended the federal 340B statute to be the sole source of the 340B Program's obligations, benefits, and operations. H.B. 2048 intrudes on that field.

H.B. 2048 Repeatedly Conflicts with Federal Law.

93. H.B. 2048 is further preempted because it conflicts with federal law. There are several flavors of conflict preemption. One of these is obstacle preemption, and H.B. 2048 is preempted under this theory because it "interferes with the methods by which . . . federal statute[s] [were] designed to reach [their] goal[s]." *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987).

94. H.B. 2048 is a quintessential drug-pricing statute—it purports to control the prices at which drugs delivered to contract pharmacies must be sold. That H.B. 2048 refers

to "delivery" and "acquisition" of 340B drugs does not change this fact. *See* Okla. Stat. tit. 36, § 5403(A). The only attribute that distinguishes a "340B" drug from a non-"340B" drug is its price. *Pharmaceutical Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 455 (S.D. W. Va. 2024) (addressing a similar West Virginia statute and finding it likely preempted by federal law).

95. That H.B. 2048 is a drug-pricing statute—and not one that regulates delivery—is evident from the fact that Novartis already continuously delivers (through its wholesaler distributors) *the very same drugs at issue to the very same pharmacies impacted by Novartis's policy*. By mandating Novartis to deliver "340B drugs" to contract pharmacies, H.B. 2048 regulates *only* the price that Novartis can charge the covered entities for those drugs. Put differently, Oklahoma regulators could assess whether a violation of H.B. 2048 has occurred only by comparing the price Novartis charged for a drug with the federal 340B ceiling price.

96. H.B. 2048 conflicts with federal law because it requires manufacturers to provide 340B pricing where the federal statute does not. The federal 340B statute does not require manufacturers to provide 340B prices on drugs to an unlimited number of contract pharmacies. *Novartis*, 102 F.4th at 461; *Sanofi*, 58 F.4th at 703; *Novartis*, 2021 WL 5161783, at *7; *AstraZeneca Pharms. LP v. Becerra*, No. 21-CV-27, 543 F. Supp. 3d 47, 61 (D. Del. 2021). But Oklahoma has effectively—if not explicitly—added contract pharmacies to the federal 340B statute as a sixteenth type of covered entity that must be offered 340B prices. *See* Okla. Stat. tit. 36, §§ 5401(2), 5403(A).

97. H.B. 2048's expansion of 340B pricing is preempted because it imposes on manufacturers "far more onerous conditions than those required by federal law." *United States v. Supreme Ct. of N.M.*, 839 F.3d 888, 928 (10th Cir. 2016); *see also Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (state law could not impose a duty not created by federal regulation).

98. Similarly, allowing Oklahoma to determine whether particular drugs should be subject to 340B pricing "would interfere with the method by which the federal statute was designed to reach its goals"—HRSA's pricing oversight of the same drugs. *Public Util. Dist. No. 1 v. IDACORP Inc.*, 379 F.3d 641, 650 (9th Cir. 2004) (finding a state law preempted where a court was asked "to set a fair price" for electricity priced by a federal agency).

99. H.B. 2048 further warps the federal 340B scheme by creating state-specific enforcement pathways that conflict with the ones Congress put in place. H.B. 2048 empowers the Oklahoma Attorney General to enforce its modifications of the 340B Program by imposing stiff fines. Okla. Stat. tit. 36, § 5404(B). But any enforcement proceeding to impose such fines will implicate the question whether each particular prescription is indeed for a 340B drug—meaning whether the hospital qualifies as a covered entity, whether the pharmacy customer is a "patient" of the covered entity, and whether the diversion prohibition has been triggered. Without addressing these issues, there would be no way of knowing whether a particular transaction involved a "340B drug." *See id.* §§ 5401(1)–(2).

100. State enforcement of federal 340B obligations is inconsistent with federal law. Congress created penalties for non-compliance, but elected not to make them so draconian that it would disincentivize participation in Medicaid and Medicare Part B. Congress explained exactly how the requirement to offer covered entities drugs at 340B prices should be enforced: (1) HHS may impose—but only for *knowing and intentional* violations—"sanctions in the form of civil monetary penalties" in specified amounts according to processes defined by regulation.[24] Or (2) covered entities may bring ADR claims alleging overcharges for 340B-eligible drugs. 42 U.S.C. § 256b(d)(3)(A). The ADR procedures, too, are exhaustively defined by regulation. 340B Drug Pricing Program, 89 Fed. Reg. 28,643 (Apr. 19, 2024); 42 C.F.R. § 10.20 *et seq*.[25]

101. When Congress expressly provides for methods of enforcing a statute, courts presume those methods are exclusive. *See, e.g.*, *Middlesex Cnty. Sewerage Auth. v. National Sea Clammers Ass'n*, 453 U.S. 1, 20 (1981). And states do not have the power to enforce federal law unless Congress clearly provides otherwise. *See, e.g.*, *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 263–264 (1972). The federal 340B statute contains no

[24] 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 1003.100 *et seq.*; 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,220 (Jan. 5, 2017).

[25] The availability of this enforcement mechanism is a concrete concern; multiple covered entities filed ADR challenges to Novartis's contract pharmacy policies, which H.B. 2048 also purports to govern. Novartis AG, *U.S. SEC Form 20-F 2024* F-45 (Jan. 30, 2025), https://tinyurl.com/5n7r3s45. HRSA has now adopted manufacturers' understanding of federal law. HRSA, *340B ADR Decision Summaries* (last updated May 15, 2025), https://tinyurl.com/2b9e24ec

suggestion that Congress intended to do so here—let alone a clear statement. *See generally* 42 U.S.C. § 256b.

102. The Supreme Court has confirmed as much. When a county that operated 340B covered entities sued manufacturers to enforce its interpretation of 340B pricing requirements, the Court held such suits were "incompatible with the statutory scheme." *Astra*, 563 U.S. at 113. It expressly adopted the Solicitor General's position regarding the federal 340B statute: "Congress centralized enforcement in the government," and allowing other entities to diffuse that power "would be inconsistent with that intent." Brief for the United States as Amicus Curiae Supporting Petitioners at 32, *Astra USA, Inc. v. Santa Clara County*, 550 U.S. 110 (2011) (No. 09-1273), https://tinyurl.com/3h8numnj; *see also Astra*, 563 U.S. at 119. Subverting that intent, moreover, "could spawn a multitude of dispersed and uncoordinated lawsuits," posing a "substantial" "risk of conflicting adjudications." *Astra*, 563 U.S. at 120.

103. The risk of conflicting adjudications here is profound. Because H.B. 2048 borrows most of its content from federal law, it cannot be enforced without answering several federal questions that HHS might answer differently.

104. What would happen if the Oklahoma Attorney General imposed liability for a transaction, but HRSA later determined in adjudicating an ADR claim that a manufacturer actually had *no* federal obligation to offer 340B pricing for the same transaction? A manufacturer would suffer sanctions for conduct federal law expressly permitted. "It is difficult to envision a more perfect collision of purposes" than for a state

to forbid something that federal law expressly "authorizes." *Maine Forest Prods. Council v. Cormier*, 51 F.4th 1, 10 (1st Cir. 2022). All the more so when the basis of that state rule is ostensibly *federal* law.

105. Another example: Who counts as a patient of the covered entity? The term "patient" is not expressly defined by the federal 340B statute, and HRSA's guidance on the subject is prolix and qualitative. It requires consideration of whether a person "receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity" and whether the "only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting." Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157–58 (Oct. 24, 1996). This issue, too, would determine whether any given prescription for which Novartis purportedly denied 340B pricing was improper under Oklahoma law. *See* 42 U.S.C. § 256b(a)(5)(B).

106. Because penalties at least appear to be assessed on a per-prescription basis, H.B. 2048 will require Oklahoma regulators to make these determinations of solely federal questions in order to determine whether a manufacturer has violated the state statute, which is itself impermissible. Further, the potential for different decisionmakers—state and federal—to reach different conclusions is plain. H.B. 2048's enforcement provisions are thus "poised to upset" 340B's " 'careful regulatory scheme established by federal law,' "

"not least by potentially leading to conflicting adjudications." *Morrisey*, 760 F. Supp. 3d at 459 (quoting *Geier*, 529 U.S. at 870); *see also id.* at 459–460 ("The fact that executing those provisions also runs the risk of producing conflicting adjudications further demonstrates what should be apparent—the Enforcement Provisions cut against the Supreme Court's holding in *Astra.*").

107. These are only examples of the thorny federal issues that H.B. 2048 foists upon state decisionmakers. H.B. 2048 is so interwoven with federal questions that it is impossible even to explain what the state law requires without referring to federal law.

108. Fracturing that interpretive power and doling it out to any jurisdiction that wishes to seize it is the antithesis of "Congress'[s] unitary administrative and enforcement scheme." *Astra*, 563 U.S. at 120. If every state enacted a law similar to H.B. 2048, that would lead to a cacophony of conflicting determinations on these fundamentally federal questions.

109. H.B. 2048 is especially harmful to federal interests given the documented lack of 340B Program integrity under the status quo. Unlawful duplication of discounts has become routine. Mundra, *supra* n19. Lack of transparency or even access to basic information—a hallmark of the replenishment model—is a key contributor to those compliance failures. *See, e.g.*, 340B House Report, *supra* n.18, at 36–37. Contract pharmacy arrangements exacerbate the situation, as the federal government has found multiple times. *E.g.*, GAO 2020 Report, *supra* ¶ 47, at 32–33; Contract Pharmacy Report, *supra* n.4, at 1–2.

110. H.B. 2048 frustrates the "twin federal purposes—providing [340B prices] to covered entities only *and* prohibiting fraud through duplicate discounts." *PhRMA v. Morrisey*, 2024 WL 5147643, at *6. That is the essence of what the Supremacy Clause forbids.

IV. H.B. 2048 Violates The Dormant Commerce Clause.

111. H.B. 2048 also violates the dormant Commerce Clause. The Commerce Clause grants Congress the power to regulate commerce among the several states. U.S. Cont. art. I, § 8, cl. 3. That power carries with it a "negative" or "dormant" restriction: Even when Congress has not exercised its commerce power, states may not "interfere with or impose burdens on interstate commerce." *Arkansas Elec. Coop. Corp. v. Arkansas Pub. Serv. Comm'n*, 461 U.S. 375, 389 (1983) (citation omitted). Statutes that purport to do so may not be enforced.

112. There are three main flavors of dormant Commerce Clause violations. A state law cannot stand if it: (1) discriminates against interstate commerce in favor of in-state commerce; (2) regulates extraterritorial transactions; or (3) imposes excessive burdens on interstate commerce. *National Pork Producers Council v. Ross*, 598 U.S. 356, 369, 376 n.1, 377–378 (2023). H.B. 2048 does all three.

H.B. 2048 Operates Extraterritorially.

113. Novartis is not located in Oklahoma. So distribution of 340B-eligible drugs from Novartis to individual pharmacies in Oklahoma necessarily takes place through a complex series of interstate transactions. Novartis typically enters into nationwide

contracts to sell its medicines to wholesalers and distributors at commercial prices. The wholesalers and distributors then sell to national chain pharmacies before the products are ultimately distributed to and dispensed by an in-state contract pharmacy out of its common inventory.

114. Under the replenishment model, the 340B discount later gets billed back to Novartis through a new transaction chain: Once a contract pharmacy's third-party administrator has purported to identify a certain number of allegedly 340B-eligible transaction, it submits a "replenishment" claim to the wholesaler, and the wholesaler arranges for the covered entity to be billed at the 340B price for the relevant number of units (whether or not it ships new product to the contract pharmacy). The wholesaler requests a refund from the manufacturer, and the manufacturer fulfills its purported 340B pricing obligation by paying the refund.

115. H.B. 2048 regulates manufacturers, not wholesalers, and broadly states that manufacturers may not even "*indirectly*" "deny, restrict, prohibit, *or otherwise interfere with*" a contract pharmacy from receiving 340B-priced product. Okla. Stat. tit. 36, § 5403(A) (emphases added). But manufacturers are giving the discount to wholesalers, and both of these entities are typically located outside of the state. H.B. 2048 therefore sets the terms of a wholly out-of-state transaction between non-Oklahoma entities.

116. The dormant Commerce Clause prohibits this kind of extraterritorial regulation. States may not directly regulate the price of transactions "beyond the boundaries of the State." *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). For this reason, the Fourth

Circuit invalidated a Maryland law that prohibited drug manufacturers or wholesale distributors from imposing "an unconscionable increase in the price of a prescription drug." *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018). As the Fourth Circuit recognized, the Maryland Act effectively sought to enforce Maryland law outside the state because it targeted the "price the manufacturer or wholesaler charge[d] *in the initial sale of the drug*," rather than the "the price the . . . consumer ultimately pays." *Id.* at 671.

117. The Eighth Circuit recently reaffirmed the same principle. Minnesota passed a drug-pricing law that applied only to manufacturers, not wholesalers. *Association for Accessible Meds. v. Ellison*, __ F.4th __, 2025 WL 1660112, at *1 (8th Cir. June 12, 2025). The Eighth Circuit noted that the unique nature of pharmaceutical distribution rendered the state law in violation of the dormant Commerce Clause. The law targeted out-of-state sales by a manufacturer to a wholesaler where the drugs are sold "at prices above those proscribed by the [state law] and those drugs later ended up in [the state]." *Id.* at *2. This is the "specific impermissible extraterritorial effect of controlling prices" that the Supreme Court has repeatedly held unlawful, and so the Eight Circuit affirmed an injunction of the Minnesota law. *Id.* at *2–3.

118. H.B. 2048 works exactly the same way. If a drug ends up at an Oklahoma pharmacy and becomes the subject of a replenishment claim, the manufacturer is forced to pay its wholesaler a chargeback to effectuate 340B pricing. The state law therefore

impermissibly "insists that out-of-state manufacturers sell their drugs to wholesalers for a certain price." *Ellison*, 2025 WL 1660112, at *2.

119. H.B. 2048 also checks all the extraterritoriality boxes the Tenth Circuit has recognized as unlawful: It is a "(1) a price control or price affirmation regulation, (2) linking in-state prices to those charged elsewhere, with (3) the effect of raising costs for out-of-state consumers or rival businesses." *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1173 (10th Cir. 2015). H.B. 2048 (1) directly controls prices because that is what it means to require delivery of a "340B drug." *Morrisey*, 760 F. Supp. 3d at 455. The statute (2) "ties the price of in-state products—prescription drugs—to the price that out-of-state manufacturers charge their wholesalers." *Ellison*, 2025 WL 1660112, at *2. And by sweeping more sales into the 340B Program than the federal program itself requires, the statute (3) drastically raises costs for manufacturers and for insurers, who often reimburse covered entities for 340B-priced drugs at much higher rates: the same rates that apply to commercially priced drugs.

120. In sum, H.B. 2048 mandates that manufacturers provide the 340B price beyond what is required under the federal 340B statute, and their only mechanism for complying is to pay chargebacks to wholesalers in purely out-of-state transactions.

H.B. 2048 Discriminates Against Interstate Commerce.

121. H.B. 2048 also violates the dormant Commerce Clause by offering a significant economic boost to in-state pharmacies at the expense of Novartis and other drug manufacturers like it. States may not engage in this kind of "economic protectionism" by

enacting regulations to benefit in-state economic interests at the expense of out-of-state competitors. *Pork Producers*, 598 U.S. at 357. State laws that discriminate against "non-resident economic actors," are invalid unless they are narrowly tailored to a legitimate local purpose. *Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 518 (2019); *see also Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (discriminatory laws are "virtually *per se* invalid").

122. By forcing out-of-state manufacturers to give steep discounts to in-state hospitals and pharmacies, going far beyond what federal law requires, H.B. 2048 impedes on interstate commerce. The "fundamental objective" of the dormant Commerce Clause is to preserve a competitive national market "undisturbed by preferential advantages" to in-state interests. *General Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997). Out-of-state manufacturers like Novartis operate within the same chain of distribution as in-state contract pharmacies and covered entities, selling the same products to a "single market" of patients and competing vertically for a share of the profit. *Id.* at 300; *see also Energy Mich., Inc. v. Michigan Pub. Serv. Comm'n*, 126 F.4th 476, 493 (6th Cir. 2025) (explaining that in-state and out-of-state interests are comparable under the dormant Commerce Clause when they compete within one market). H.B. 2048 seeks to disrupt that balance, forcing out-of-state manufacturers to subsidize in-state entities that Congress did not see fit to make beneficiaries of the federal 340B program.

123. H.B. 2048's goal is to generate greater revenue for in-state pharmacies and covered entities by forcing out-of-state manufacturers to give them steep discounts beyond

what is required of them under the federal 340B program. This is evident from three lawmakers who supported the bill. After Governor Stitt's veto, they sharply criticized the move in a public statement that explicitly denigrated "[o]ut-of-state and foreign drug companies and the dark money interests working for them." Oklahoma H.R., *Stinson, Howard Comment on Governor's Veto of Bill to Protect Rural Health Care* (May 21, 2025), https://tinyurl.com/mhyh7x8y. Animus against non-Oklahoma entities does not get much clearer than that. And the lawmakers admitted that the bill would amount to a transfer of economic benefit to "rural Oklahomans" from what they called "the $7 trillion drug industry." *Id.* But the dormant Commerce Clause prohibits Oklahoma from engaging in this type of flagrant protectionism simply because one party is a constituent and the other is not.

124. Nor is there a legitimate justification for Oklahoma to discriminate against out-of-state manufacturers. Novartis's policy complies with the federal 340B statute, as explicitly upheld by a federal circuit court. It allows covered entities to dispense their discounted drugs through a contract pharmacy—even though the federal statute does not require this—just not an unlimited number of them. *See* Ex. 1 (2025 Policy). And it even exempts federal grantees from this limitation entirely. *Id.* Federal law unequivocally permits Novartis to impose such reasonable business conditions on 340B pricing. *Novartis Pharms. Corp.*, 102 F.4th at 463–464; *Sanofi Aventis*, 58 F.4th at 703–706.

125. Moreover, the benefits from unlimited contract pharmacy arrangements do not run to patients or the public. *Supra* ¶¶ 7, 18, 13, 38 (explaining that almost all patients

pay the same prices irrespective of whether their prescriptions are later used to claim 340B pricing).[26] Novartis, through its wholesalers, *already delivers* the very same drug products to the very same pharmacies, which routinely dispense them without regard to whether a patient is 340B-eligible. H.B. 2048 governs only the price of the sale to the covered entity and contract pharmacy (not to the patient, who pays her insurance company's predetermined copay). Further, as more and more contract entities take advantage of these types of statutes—as has already been occurring—the revenue generated from the 340B discount falls increasingly in the hands of for-profit pharmacies and third-party administrators. *See, e.g.*, Minnesota Dep't of Health, *supra* n.8, at 9. Other, more targeted means, such as direct grants to hospitals and pharmacies, would better support these entities without discriminating against interstate commerce.

H.B. 2048 Impermissibly Burdens Interstate Commerce.

126. H.B. 2048 likewise fails under the balancing test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The bill forcibly shifts the bargaining power along the distribution chain by requiring out-of-state drug manufacturers to subsidize in-state industries. Even if the purpose of H.B. 2048 were not to discriminate against out-of-state manufacturers like Novartis, the substantial burden it imposes on interstate commerce is

[26] *See also, e.g.*, Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33(10) H. Aff. 1786 (Oct. 2014) ("Our findings are consistent with recent complaints . . . suggesting that the 340B program is being converted from one that serves vulnerable communities to one that enriches participating hospitals and the clinics affiliated with them."), https://tinyurl.com/ycxatjb7.

excessive compared to the purported local benefits. *V-1 Oil Co. v. Utah State Dep't of Pub. Safety*, 131 F.3d 1415, 1423–24 (10th Cir. 1997); *Forever Fencing, Inc. v. Board of Cnty. Comm'rs of Leavenworth Cnty.*, No. 23-3140, 2024 WL 3084793, at *3 (10th Cir. June 21, 2024) (recognizing post-*Pork Producers* that even non-discriminatory state laws may run afoul of *Pike*).

127. By meddling with what was meant to be a national drug-pricing program, H.B. 2048 ratchets up administrative burdens on manufacturers and wholesalers, who must now make state-specific exceptions to formerly national contract pharmacy policies if they wish to remain in compliance with this patchwork of state laws. This "lack of uniformity in state laws" falls entirely on non-Oklahoma entities—a direct burden on shipping drugs into the state. *V-1 Oil*, 131 F.3d at 1425 (quoting *Pacific Nw. Venison Prods. v. Smitch*, 20 F.3d 1008, 1015 (9th Cir. 1994)). And the Court must also consider the burden that would arise if "many or every, State adopted similar legislation." *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992) (quoting *Healy*, 491 U.S. at 336).

128. That is no longer a hypothetical problem for the 340B Program. H.B. 2048 and other state laws like it collectively unleash havoc on nationwide drug distribution. Novartis typically sells its products by entering into nationwide contracts with wholesalers and distributors, who in turn contract with pharmacies down the distribution chain. State-specific pricing laws like H.B. 2048 interfere with interstate distribution and impose conflicting requirements on drug manufacturers and their wholesalers and distributors.

129. Manufacturers, wholesalers, and distributors must wade through this deepening mire that increasingly threatens to transform nationwide drug distribution into a litany of state-specific distribution systems. As Oklahoma and other states continue to enact conflicting 340B laws, Novartis will be unable to implement the federal 340B program on a uniform, nationwide basis. State-specific 340B requirements raise the administrative cost of providing drugs, as Novartis must prepare contract pharmacy policies that satisfy overlapping and inconsistent laws.

130. The burden on interstate drug distribution continues to increase as more and more states enact their own versions of 340B laws. Already, Arkansas, Colorado, Kansas, Louisiana, Maine, Maryland, Mississippi, Minnesota, Missouri, Nebraska, New Mexico, North Dakota, Rhode Island, South Dakota, Tennessee, Utah, and West Virginia have enacted similar laws.[27] One does not need to be an expert in drug distribution to see the problem. *See Frosh*, 887 F.3d at 673 (holding that a drug-pricing statute disproportionately burdened interstate commerce when it had "the potential to subject prescription drug manufacturers to conflicting state requirements"). This is exactly the compounding burden on interstate commerce that the dormant Commerce Clause prohibits.

[27] Arkansas (Ark. Code § 23-92-601 *et seq.*); Colorado (Colo. R.S. § 6-29-101 *et seq.*); Hawaii (H.B. 712 (2025)); Kansas (Kan. Stat. § 65-483); Louisiana (La. Rev. Stat. § 40:2883); Maine (L.D. 210 pt. P (2025)); Maryland (H.B. 1056 (2024)); Minnesota (H.F. 4991 (2024)); Mississippi (Miss. Code § 75-24-5); Missouri (H.B. 728 (2024)); Nebraska (Neb. L.B. 168, § 3(1) (2025)); New Mexico (N.M. H.B. 78 (2025)); North Dakota (N.D. Cent. Code § 43-15.3-08); Oregon (H.B. 2385 (2025)); Rhode Island (S.B. 114 (2025)); South Dakota (S.B. 154 (2025)); Tennessee (S.B. 1414 (2025)); Utah (Utah Code § 31A-46-311); Vermont (H.266 (2025)); and West Virginia (W. Va. Code § 60A-8-6a).

V. H.B. 2048 Will Cause Novartis Imminent, Irreparable Harm.

131. Novartis will be irreparably harmed if H.B. 2048 is enforced.

132. H.B. 2048 puts Novartis in a lose-lose situation. On one hand, complying with the law will require Novartis to expend significant resources to satisfy requirements imposed by an unconstitutional law. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992). There is no way for Novartis to recover these compliance costs, and as more and more states enact similar 340B laws, the administrative burden to comply with each law will only increase.

133. Being subject to an unconstitutional law is itself a significant irreparable harm. *Free Speech Coal., Inc. v. Shurtleff*, No. 2:05-CV-949, 2007 WL 922247, at *18 (D. Utah Mar. 23, 2007) (identifying "deprivation of the rights guaranteed under the Commerce Clause" and "permitting states to regulate where Congress has preempted state regulation" as irreparable harms (quotations omitted and alteration adopted)). That is especially so here, where H.B. 2048 undermines Novartis's ability to rely on rights conferred by federal law to structure its conduct. *See Novartis*, 102 F.4th at 463–464; *Sanofi*, 58 F.4th at 703–706.

134. Beyond that, H.B. 2048 will cause Novartis to lose millions of dollars as it provides discounted prices that the federal statute does not require it to offer. In many instances, these discounts will violate the federal statute's prohibitions on duplication or diversion.

135. The state of Oklahoma cannot be held directly liable for these damages because it is protected by sovereign immunity. "Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury." *Chamber of Com. of the U.S.*, 594 F.3d at 770–771 (citing *Kansas Health Care Ass'n, Inc. v. Kansas Dep't of Social & Rehab. Servs.*, 31 F.3d 1536, 1543 (10th Cir. 1994)).

136. Failing to comply with H.B. 2048, on the other hand, exposes Novartis to costly enforcement actions and severe penalties. Novartis could be subject to fines of up to $10,000 "for each violation"—which might be interpreted to mean each drug dispensed at a contract pharmacy for which a covered entity demands the 340B price. *See* Okla. Stat. tit. 36, § 5404(B). Regardless of the penalty imposed, any enforcement action will require Novartis to expend significant resources defending itself or its employees. None of those sanctions or costs could ever be recovered.

137. Whether or not Novartis complies with H.B. 2048, it must divert substantial resources from research and development of new drug therapies. Those opportunity costs, too, can never be regained.

138. Injunctive relief will preserve the status quo and cause no harm to Defendant. Oklahoma has "no cognizable state interest in enforcing state laws preempted by federal law." *Seneca-Cayuga Tribe of Okla. v. State of Okla. ex rel. Thompson*, 874 F.2d 709, 716 (10th Cir. 1989) (quotation omitted and alteration adopted). States generally have, at most, a *de minimis* interest in enforcing laws and policies deemed unconstitutional for any reason.

See, e.g., *Black Emergency Response Team v. Drummond*, 737 F. Supp. 3d 1136, 1157 (W.D. Okla. 2024) ("[T]he State has no legitimate interest in enforcing a law determined to be unconstitutionally vague.").

139. Injunctive relief will also serve the public interest by maintaining the integrity of a carefully planned federal program. *See, e.g.*, *United States v. Alabama*, 691 F.3d 1269, 1301 (11th Cir. 2012) ("Frustration of federal statutes and prerogatives are not in the public interest."); *Bioganic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1168, 1179 (D. Colo. 2001) (finding the public interest favored enjoining enforcement of a preempted state statute because "Congress has already found that exclusive federal regulation . . . is in the public interest"). Likewise, "the public interest is not harmed by preliminarily enjoining the enforcement of a statute that is probably unconstitutional." *Evans v. Utah*, 21 F. Supp. 3d 1192, 1210 (D. Utah 2014) (quotation omitted).

140. The public will also benefit from an injunction ensuring Novartis can direct its resources where they are most needed: researching and developing new drug therapies for patients.

COUNT I
(Federal Field Preemption | U.S. Const. art. VI, cl. 2)

141. Novartis realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

142. Federal law is "the supreme Law of the Land; . . . any Thing in the . . . Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

143. Congress has determined that the federal 340B Drug Pricing Program must be regulated by its exclusive governance. The obligations imposed by the federal 340B statute—and just as importantly, those *not* imposed by the federal 340B statute—are a critical part of Congress's overall involvement in the nationwide pharmaceutical market. States are not free to reconfigure that level of involvement, regardless of whether they perceive Congress's limits as "silence."

144. Consistent with the 340B Program's exclusively federal domain, the federal 340B statute contains a pervasive framework of federal regulation including an exhaustive definition of the types of entities that are eligible for discounted prices, limitations on when those entities can receive discounted pricing, limitations on what those entities can do with discounted drugs, and a comprehensive remedial scheme that provides for federal enforcement and private ADR claims under the oversight of a federal agency.

145. The federal interest in regulating 340B-priced drugs is also so dominant that Congress's statutory scheme precludes state regulation covering the same subject. As the Supreme Court has already recognized, state attempts to interfere in this realm are "incompatible with the [340B] statutory regime." *Astra*, 563 U.S. at 113.

146. H.B. 2048 expressly targets the field of "the federal 340B drug discount program." *See, e.g.*, Okla. Stat. tit. 36, § 5401(2). Each of its provisions therefore implicates a legislative field that Congress has reserved for its exclusive governance.

147. H.B. 2048 therefore violates the Supremacy Clause of the U.S. Constitution.

COUNT II
(Federal Conflict Preemption | U.S. Const. art. VI, cl. 2)

148. Novartis realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

149. H.B. 2048 repeatedly frustrates the purposes of multiple federal statutes and interferes with the methods by which those federal statutes attempt to achieve their goals.

150. H.B. 2048 directly regulates drug pricing by requiring Novartis to provide a discounted price on drugs delivered to an unlimited number of contract pharmacies.

151. In this way, H.B. 2048 requires Novartis to offer deeply discounted pricing in situations where the federal 340B statute does not, and therefore expands the size of the federal 340B Drug Pricing Program, imposing requirements more onerous than those of federal law.

152. H.B. 2048 purports to overwrite several tradeoffs Congress made in passing the federal 340B statute. H.B. 2048 interferes with federal objectives and methods by: preventing Novartis from exercising its federal-statutory discretion to set reasonable conditions on 340B pricing; forcing Novartis to provide 340B pricing for more products; fracturing the federal statute's centralized enforcement scheme; creating a risk of conflicting adjudications of federal law; and perpetuating rampant noncompliance with the federal prohibitions on duplication and diversion.

153. H.B. 2048 therefore violates the Supremacy Clause of the U.S. Constitution.

COUNT III
(Dormant Commerce Clause | U.S. Const. art. I, § 8, cl. 3)

154. Novartis realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

155. Under the Commerce Clause, Congress has the power to regulate commerce among the several states. U.S. Const. art. I, § 8, cl. 3. The corresponding "dormant" Commerce Clause prevents states from imposing regulations that discriminate against interstate commerce, unduly burden it, or regulate commerce occurring entirely out of state.

156. H.B. 2048 violates the dormant Commerce Clause by regulating wholly out-of-state transactions between drug manufacturers like Novartis and out-of-state wholesalers.

157. H.B. 2048 also intentionally discriminates against interstate commerce by benefitting in-state healthcare providers and pharmacies at the expense of out-of-state manufacturers. This blatant economic protectionism violates the dormant Commerce Clause.

158. There is no legitimate local purpose for discriminating against out-of-state manufacturers like Novartis, and even if there were, there are other, less burdensome means available to Oklahoma to advance that purpose.

159. H.B. 2048 additionally fails the balancing test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). This Oklahoma law and others like it impose a substantial harm on interstate commerce by imposing burdensome and conflicting requirements on drug manufacturers that impede the national distribution of pharmaceutical drugs. The burden on interstate commerce is clearly excessive in relation to the purported local

benefit and will only continue to increase as more states enact their own state 340B programs.

160. H.B. 2048 therefore violates the Commerce Clause of the U.S. Constitution.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration under 28 U.S.C. § 2201 that H.B. 2048 is preempted by federal law and is thus null, void, and unenforceable;

B. A declaration under 28 U.S.C. § 2201 that H.B. 2048 violates the dormant Commerce Clause and is thus null, void, and unenforceable;

C. Preliminary and permanent injunctive relief vacating H.B. 2048 and enjoining Defendant from implementing or enforcing H.B. 2048 against Novartis or any of its affiliates, officers, agents, representatives, or contractors;

D. Preliminary and permanent injunctive relief enjoining Defendant from seeking civil penalties, equitable relief, or any other remedy arising from an alleged violation of H.B. 2048 by Novartis or any of its affiliates, officers, agents, representatives, or contractors;

E. An order awarding Novartis its costs, expenses, and attorney's fees incurred in these proceedings; and

F. Such other and further relief as the Court deems proper.

DATED: June 30, 2025

Respectfully submitted,

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**Motion for admission pro hac vice forthcoming*

VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct.

Executed this 27th day of June 2025.

Shannon McCrudden